

## **REMARKS/ARGUMENTS**

Applicants have received the Office Action dated December 19, 2007, in which the Examiner: 1) rejected claims 1, 3, 4, 8, 15, 18, 32, 33 and 38-46 under 35 U.S.C. § 102(b) as being allegedly anticipated by Voss et al. (U.S. Pat. No. 4,322,449, hereinafter "Voss"); and 2) rejected claims 2, 5-7, 9-14, 16, 17 and 35-37 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Voss in view of Stimpson et al. (BioTechniques 25:886-890 November 1998, hereinafter "Stimpson"). With this Response, Applicants have amended claims 1-3 to better clarify the invention. Claim 49 was also added to better state the invention. No new matter is added by these amendments. Applicants have also canceled the previously withdrawn claims (19-31 and 46-48). Applicants believe all pending claims are allowable over the art of record and respectfully request reconsideration and allowance of all claims.

### **I. REJECTIONS UNDER 35 U.S.C. § 102(b)**

The Examiner has rejected claims 1, 3, 4, 8, 15, 18, 32, 33 and 38-46 under 35 U.S.C. § 102(b) as being anticipated by Voss. In order to establish a prima facie case of anticipation, the Examiner must show that each and every element of the claims is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). If a single element is not found in the prior art reference, the claims are not anticipated. Applicants respectfully disagree that Voss anticipates claims 1, 3, 4, 8, 15, 18, 32, 33 and 38-46.

Claims 1, 4, and 32 are independent claims upon which claims 3, 8, 15, 18, 33 and 38-46 depend, respectively. Claim 1, as amended, recites "adjusting one or more deposition characteristics of the plurality of substantially uniformly sized dots to control the dissolution rate." Claim 4 recites "selecting a desired dot size corresponding to a target dissolution rate." Claim 32 recites "setting an application parameter based on a target dissolution rate." Nothing in Voss expressly discloses a target dissolution rate based on one or more deposition characteristics, an application parameter, or dot size.

In the Office Action, the Examiner states “[t]he limitation of selecting a target dissolution rate is an inherent feature of ‘the extremely precise dosing of active pharmaceutical ingredients.’” The Examiner further argues because “the limitation of applying a bioactive agent to a delivery substrate as a plurality of dots is anticipated by *Voss*, the method of controlling a dissolution rate of a bioactive agent (comprising these limitations) is also anticipated by *Voss*.” Thus, the Examiner appears to be arguing that control of dissolution rate and dosing are one and the same, which is simply not the case.

In order to show inherency, the Examiner must “provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic ***necessarily flows*** from the teachings of the applied prior art.” Manual of Patent Examining Procedure § 2112 (2007) (citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)) (Emphasis added). It is not sufficient for the Examiner merely to show that “a result or characteristic ***may*** occur or be present in the prior art.” MPEP § 2112 (citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)) (Emphasis added).

As disclosed on page 12 of the Specification, dissolution rate is dependent on many factors other than mere dose. For example, the Specification lists deposition characteristics as “dot size, dot geometric surface area, dot mass, dot surface-to-mass ratio, dot topography, dot topographic surface area, dot geometry, dot layering” among other characteristics which may influence dissolution rate. *Voss* does not describe the use of deposition characteristics or application parameters as a means of controlling dissolution rate, much less suggest that these variables are even a factor in determining dissolution rate. Instead, *Voss* is primarily concerned with applying a specific volume of liquid on to a surface, irregardless of dissolution rate. Thus, it does not follow that the dosing of active pharmaceutical ingredients taught in *Voss* will necessarily result in control of dissolution rate.

In addition, Applicants submit that *Voss* discloses only use of continuous ink ejectors, an old technology. *Voss*, col. 4, Ins. 57-68 & Figure 3. Continuous

ink ejectors generate a steady stream of ink, deflecting drops electronically onto a medium. The continuous flow makes image resolution difficult to control. One of ordinary skill in the art would understand that the technology taught in *Voss* would not be capable of the precision and control of deposition characteristics necessary for controlling or attaining a target dissolution rate.

In view of the above reasons, *Voss* does not disclose each and every element, expressly or inherently, of independent claims 1, 4, and 32, and, thus, does not anticipate claims 1, 4, and 32 or dependent claims 3, 8, 15, 18, 33 and 38-46. Accordingly, the Applicants respectfully request withdrawal of this rejection.

## **II. REJECTIONS UNDER 35 U.S.C. § 103(a)**

Applicants traverse the rejections of claims 2, 5-7, 9-14, 16, 17 and 35-37 under 35 U.S.C. § 103(a) as being unpatentable over *Voss* in view of *Stimpson*. “The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.” See MPEP § 2143 (2007). To establish obviousness, each of the claim limitations must be taught or suggested by the prior art. See *CFMT, Inc. v. YieldUp Int’l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). In addition, “[i]f an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.” MPEP § 2143.03 (2007) (citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Applicants respectfully submit that a case of obviousness has not been established in rejecting claims 2, 5-7, 9-14, 16, 17 and 35-37.

Claims 2, 5-7, 9-14, 16, 17 and 35-37 are dependent on independent claims 1, 4, and 32, respectively. As explained above in Section II, *Voss* does not teach each and every element, either expressly or inherently of claims 1, 4, and 32 because *Voss* does not teach or suggest a target dissolution rate. Rather, *Voss* is solely concerned with overall exact dosing of pharmaceuticals. *Voss*, col. 1, Ins. 63-66. As such, *Voss* does not teach, inherently or expressly, all the claim limitations.

*Voss* in combination with *Stimpson* also does not teach or suggest the claim limitations. In fact, *Stimpson* does not have anything to do with a target dissolution rate. Instead, *Stimpson* is directed to using thermal or piezoelectric inkjet printing to deposit lines of DNA material for scientific and research analysis. The DNA lines are used for hybridization experiments involving specific DNA sequences. Thus, contrary to claims 1, 4, and 32, *Stimpson* desires the printed DNA lines to remain on the print medium rather than control or attain target dissolution rate. As a result, *Stimpson* cannot supply *Voss* with the missing limitations.

Applicants therefore respectfully submit that the Examiner has not shown obviousness in rejecting claims 2, 5-7, 9-14, 16, 17 and 35-37, because the cited references do not teach or suggest all of the elements recited in the rejected claims. Since independent claims 1, 4, and 32 are submitted to be allowable, dependent claims 2, 5-7, 9-14, 16, 17 and 35-37 must *a fortiori* also be allowable, as they carry with them all the limitations of claims 1, 4, and 32. Accordingly, Applicants respectfully request that the Examiner withdraw the § 103 rejections and allow claims 2, 5-7, 9-14, 16, 17 and 35-37.

### **III. CONCLUSION**

Applicants respectfully request reconsideration, allowance of the pending claims and a timely Notice of Allowance be issued in this case. If the Examiner feels that a telephone conference would expedite the resolution of this case, the Examiner is respectfully requested to contact the undersigned.

In the course of the foregoing discussions, Applicants may have at times referred to claim limitations in shorthand fashion, or may have focused on a particular claim element. This discussion should not be interpreted to mean that the other limitations can be ignored or dismissed. The claims must be viewed as a whole, and each limitation of the claims must be considered when determining the patentability of the claims. Moreover, it should be understood that there may be other distinctions between the claims and the cited art which have yet to be raised, but which may be raised in the future.

**Appl. No. 10/801,380**  
**Amdt. dated March 19, 2008**  
**Reply to Office Action of December 19, 2007**

Applicants respectfully request reconsideration and that a timely Notice of Allowance be issued in this case. It is believed that no extensions of time or fees are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required (including fees for net addition of claims) are hereby authorized to be charged to Hewlett-Packard Development Company's Deposit Account No. 08-2025.

Respectfully submitted,

/Albert Shung/

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